

INOVIO PHARMACEUTICALS, INC.

Form 10-Q

November 09, 2015

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

OR  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_  
COMMISSION FILE NO. 001-14888

INOVIO PHARMACEUTICALS, INC.  
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE 33-0969592  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

660 W. GERMANTOWN PIKE, SUITE 100  
PLYMOUTH MEETING, PA 19462

(Address of principal executive offices) (Zip Code)  
REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (267) 440-4200  
SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:  
COMMON STOCK, \$0.001 PAR VALUE NASDAQ  
(Title of Class) (Name of Each Exchange on Which Registered)  
SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The number of shares outstanding of the Registrant's Common Stock, \$0.001 par value, was 72,183,247 as of November 2, 2015.

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INOVIO PHARMACEUTICALS, INC.  
FORM 10-Q

For the Quarterly Period Ended September 30, 2015

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## Part I. Financial Information

## Item 1. Financial Statements

## INOVIO PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$85,468,796	\$40,543,982
Short-term investments	85,313,556	53,075,974
Accounts receivable	10,965,273	2,804,207
Prepaid expenses and other current assets	1,348,890	797,973
Prepaid expenses and other current assets from affiliated entity	634,326	1,382,375
Deferred tax asset	342,573	342,573
Total current assets	184,073,414	98,947,084
Fixed assets, net	6,458,900	4,583,204
Investments in affiliated entities	25,321,361	12,340,811
Intangible assets, net	4,118,010	4,776,059
Goodwill	10,113,371	10,113,371
Common stock warrants	88,900	550,000
Other assets	597,570	474,568
Total assets	\$230,771,526	\$131,785,097
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$10,519,408	\$6,383,170
Accounts payable and accrued expenses due to affiliated entity	2,813,019	28,407
Accrued clinical trial expenses	2,942,444	2,007,432
Common stock warrants	1,093,752	2,022,729
Deferred revenue	188,415	3,187,223
Deferred revenue from affiliated entity	523,192	394,791
Deferred rent	197,642	—
Total current liabilities	18,277,872	14,023,752
Deferred revenue, net of current portion	12,798,493	173,779
Deferred revenue from affiliated entity, net of current portion	798,532	836,694
Deferred rent, net of current portion	5,007,000	4,709,229
Deferred tax liabilities	504,049	504,049
Total liabilities	37,385,946	20,247,503
Inovio Pharmaceuticals, Inc. stockholders' equity:		
Common stock	72,181	60,741
Additional paid-in capital	532,559,242	443,327,915
Accumulated deficit	(343,145,851 )	(331,910,290 )
Accumulated other comprehensive income (loss)	3,654,180	(251,390 )
Total Inovio Pharmaceuticals, Inc. stockholders' equity	193,139,752	111,226,976
Non-controlling interest	245,828	310,618
Total stockholders' equity	193,385,580	111,537,594
Total liabilities and stockholders' equity	\$230,771,526	\$131,785,097

See accompanying notes to unaudited condensed consolidated financial statements.



INOVIO PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Revenue under collaborative research and development arrangements	\$ 16,475,083	\$ 1,114,952	\$ 25,055,890	\$ 5,658,460
Revenue under collaborative research and development arrangements with affiliated entity	125,000	112,500	404,167	366,964
Grants and miscellaneous revenue	7,583,151	612,901	9,176,492	1,974,234
Total revenues	24,183,234	1,840,353	34,636,549	7,999,658
Operating expenses:				
Research and development	16,075,201	7,017,805	42,190,032	24,850,566
General and administrative	4,377,616	3,153,714	13,203,804	11,633,259
Gain on sale of assets	—	—	(1,000,000 )	—
Total operating expenses	20,452,817	10,171,519	54,393,836	36,483,825
Income (Loss) from operations	3,730,417	(8,331,166 )	(19,757,287 )	(28,484,167 )
Other income (expense):				
Interest and other income, net	214,982	97,174	499,590	218,249
Change in fair value of common stock warrants	518,877	(113,980 )	467,877	204,484
Gain (loss) on investment in affiliated entity	(659,054 )	1,168,911	5,849,782	(666,212 )
Net income (loss) before income tax benefit	3,805,222	(7,179,061 )	(12,940,038 )	(28,727,646 )
Income tax benefit	1,789,246	—	1,789,246	—
Net income (loss)	5,594,468	(7,179,061 )	(11,150,792 )	(28,727,646 )
Net (income) loss attributable to non-controlling interest	—	1,486	(84,769 )	17,337
Net income (loss) attributable to Inovio Pharmaceuticals, Inc.	\$ 5,594,468	\$ (7,177,575)	\$ (11,235,561)	\$ (28,710,309)
Net income (loss) per common share attributable to Inovio Pharmaceuticals, Inc. stockholders:				
Basic	\$0.08	\$(0.12 )	\$(0.17 )	\$(0.49 )
Diluted	\$0.07	\$(0.12 )	\$(0.18 )	\$(0.52 )
Weighted average number of common shares outstanding used in per share calculations:				
Basic	72,029,644	60,392,911	66,846,481	58,625,740
Diluted	73,961,237	60,602,831	67,018,961	58,936,414

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.  
 CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)  
 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income (loss)	\$5,594,468	\$(7,179,061)	\$(11,150,792)	\$(28,727,646)
Other comprehensive income (loss):				
Unrealized gain on investment in affiliated entity, net of tax	3,998,521	—	3,998,521	—
Foreign currency translation adjustments	—	—	—	(1,689 )
Unrealized loss on short-term investments, net of tax	(20,149 )	(62,813 )	(92,951 )	(32,122 )
Comprehensive income (loss)	9,572,840	(7,241,874 )	(7,245,222 )	(28,761,457 )
Comprehensive (income) loss attributable to non-controlling interest	—	1,486	(84,769 )	17,337
Comprehensive income (loss) attributable to Inovio Pharmaceuticals, Inc.	\$9,572,840	\$(7,240,388)	\$(7,329,991 )	\$(28,744,120)

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.  
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
 (Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(11,150,792 )	\$(28,727,646 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	733,722	428,801
Amortization of intangible assets	658,049	712,121
Change in value of common stock warrants	(467,877 )	(204,484 )
Stock-based compensation	4,900,898	4,548,445
Issuance of shares in connection with reverse stock split	—	57,187
Amortization of premiums on investments	242,384	—
Deferred rent	308,840	589,109
Loss on disposal of fixed assets	7,899	2,959
Loss on short-term investments	1,183	1,500
(Gain) Loss on investment in affiliated entity	(5,849,782 )	666,212
Gain on sale of intangible assets	(1,000,000 )	—
Income tax benefit from other unrealized gains on securities	(1,789,246 )	—
Changes in operating assets and liabilities:		
Accounts receivable	(8,161,066 )	1,679,569
Prepaid expenses and other current assets	(550,917 )	51,758
Prepaid expenses and other current assets from affiliated entity	748,049	468,147
Restricted cash	—	100,762
Other assets	(123,002 )	—
Accounts payable and accrued expenses	3,325,939	(970,886 )
Accounts payable and accrued expenses due to affiliated entity	2,784,612	(428,005 )
Deferred revenue	9,625,906	(468,404 )
Deferred revenue from affiliated entity	90,239	(256,251 )
Net cash used in operating activities	(5,664,962 )	(21,749,106 )
Cash flows from investing activities:		
Purchases of investments	(37,391,913 )	(19,288,154 )
Maturities of investments	4,745,000	7,900,855
Purchases of capital assets	(1,955,621 )	(1,207,874 )
Proceeds from sale of intangible assets	1,000,000	—
Net cash used in investing activities	(33,602,534 )	(12,595,173 )
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	81,902,363	59,209,182
Proceeds from stock option and warrant exercises	2,439,506	12,085,990
Other financing activities	(149,559 )	—
Net cash provided by financing activities	84,192,310	71,295,172
Effect of exchange rate changes on cash and cash equivalents	—	(1,689 )
Increase in cash and cash equivalents	44,924,814	36,949,204
Cash and cash equivalents, beginning of period	40,543,982	33,719,796
Cash and cash equivalents, end of period	\$85,468,796	\$70,669,000
Supplemental disclosure of non-cash activities		
Amounts accrued for purchases of property and equipment	\$475,123	\$89,539



Lease incentive recorded as fixed assets and deferred rent	\$186,573	\$933,350
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See accompanying notes to unaudited condensed consolidated financial statements.

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INOVIO PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Operations

Inovio Pharmaceuticals, Inc. (the “Company” or “Inovio”), a clinical stage biopharmaceutical company, develops active DNA immunotherapies and vaccines in combination with proprietary electroporation delivery devices to prevent and treat cancers and infectious diseases. Inovio’s synthetic products are based on the Company’s SynCon® design. The Company has completed, current or planned clinical programs of its proprietary SynCon® products for HPV-caused pre-cancers and cancers, influenza, prostate cancer, breast/lung/pancreatic cancer, hepatitis C virus (HCV), hepatitis B virus (HBV), HIV, and Ebola. The Company’s partners and collaborators include F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (“Roche”), University of Pennsylvania, Drexel University, National Microbiology Laboratory of the Public Health Agency of Canada, National Institute of Allergy and Infectious Diseases (“NIAID”), United States Military HIV Research Program (“USMHRP”), U.S. Army Medical Research Institute of Infectious Diseases (“USAMRIID”), HIV Vaccines Trial Network (“HVTN”), Defense Advanced Research Projects Agency (“DARPA”) and MedImmune, LLC. Inovio is incorporated in Delaware.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Inovio have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of September 30, 2015, condensed consolidated statements of operations for the three and nine months ended September 30, 2015 and 2014, condensed consolidated statements of comprehensive income (loss) for the three and nine months ended September 30, 2015 and 2014 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014, are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2015 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2015, or for any other period. These financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2014, included in the Company’s Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 13, 2015. The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The Company has evaluated subsequent events after the balance sheet date of September 30, 2015 through the date it filed these unaudited condensed consolidated financial statements with the SEC.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

3. Impact of Recently Issued Accounting Standards

The recent pronouncements below may have a significant effect on the Company’s financial statements. Recent pronouncements that are not anticipated to have an impact on or are unrelated to the Company’s financial condition, results of operations, or related disclosures are not discussed.

Accounting Standards Update (“ASU”), No. 2014-15- In August 2014, the Financial Accounting Standards Board (the “FASB”), issued ASU 2014-15, which intends to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related disclosure. ASU 2014-15 defines the term substantial doubt and requires an assessment for a period of one year after the date of the issuance of the financial statements. It requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The guidance becomes effective for reporting periods beginning after December 15, 2016, with early

adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements and related disclosures.

ASU, No. 2014-09- In May 2014, the FASB amended the existing accounting standards for revenue recognition, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that

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reflects the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The amended guidance as currently issued will be effective for the Company starting in 2018. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of determining the adoption method it will implement, as well as the effects the adoption will have on its financial statements and related disclosures.

#### 4. Principles of Consolidation

These unaudited condensed consolidated financial statements include the accounts of Inovio Pharmaceuticals, Inc. and its subsidiaries. In conjunction with the acquisition in June 2009 of VGX Pharmaceuticals (the "Merger"), the Company acquired a majority interest in VGX Animal Health and certain shares in GeneOne Life Sciences ("GeneOne") (a publicly-traded company in South Korea). The Company consolidates Genetronics, Inc. (a wholly-owned subsidiary of Inovio Pharmaceuticals, Inc.), VGX Pharmaceuticals and its subsidiary VGX Animal Health and records a non-controlling interest for the 15% and 9% of VGX Animal Health it does not own as of September 30, 2015 and December 31, 2014, respectively. The Company's investment in GeneOne, which is recorded as investment in affiliated entity within the condensed consolidated balance sheets is accounted for at fair value on a recurring basis, with changes in fair value recorded on the condensed consolidated statements of operations within gain (loss) on investment in affiliated entity. All intercompany accounts and transactions have been eliminated upon consolidation.

##### Variable Interest Entities

In June 2009, the FASB issued authoritative guidance that requires companies to perform a qualitative analysis to determine whether a variable interest in another entity represents a controlling financial interest in a variable interest entity. A controlling financial interest in a variable interest entity is characterized by having both the power to direct the most significant activities of the entity and the obligation to absorb losses or the right to receive benefits of the entity. This guidance also requires on-going reassessments of variable interests based on changes in facts and circumstances. This guidance became effective for fiscal years beginning after November 15, 2009. The Company adopted the provisions of the guidance in the first quarter of 2010 and determined that none of the entities with which the Company currently conducts business and collaborations are variable interest entities, except VGXI (a wholly-owned subsidiary of GeneOne) and Plumblin Life Sciences, Inc. ("PLS") (See Note 11). The Company determined that they are not the primary beneficiary and therefore are not required to consolidate VGXI or PLS. The Company continues to assess its variable interests and has determined that no significant changes have occurred as of September 30, 2015.

#### 5. Investments

Investments consist of mutual funds, United States corporate debt securities, municipal bonds and an equity investment in the Company's affiliated entity PLS at September 30, 2015 and mutual funds and United States corporate debt securities at December 31, 2014. The Company classifies all investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive income (loss) until realized. Realized gains and losses are included in non-operating other income (expense) on the condensed consolidated statement of operations and are derived using the specific identification method for determining the cost of the securities sold. During the three and nine months ended September 30, 2015 and 2014, a minimal amount of net realized loss on investments was recorded. Interest and dividends on investments classified as available-for-sale are included in interest and other income, net, in the condensed consolidated statements of operations. As of September 30, 2015, the Company had 56 available-for-sale securities in a gross unrealized loss position of which 6 were in such position for longer than 12 months. There were no impairments considered to be other-than-temporary as the Company has the ability and intent to hold the securities until recovery of the cost basis. The following is a summary of available-for-sale securities as of September 30, 2015 and December 31, 2014:



	Contractual Maturity (in years)	As of September 30, 2015			
		Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	\$58,633,654	\$—	\$ (398,320)	) \$ 58,235,334
US corporate debt securities	Less than 2	26,993,900	6,052	(24,873)	) 26,975,079
Municipal bonds	Less than 1	103,156	—	(13)	) 103,143
Investment in affiliated entity (PLS)	---	—	7,130,768	—	7,130,768
Total investments		\$85,730,710	\$ 7,136,820	\$ (423,206)	) \$ 92,444,324
	Contractual Maturity (in years)	As of December 31, 2014			
		Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	\$29,487,758	\$ 2,667	\$ (216,790)	) \$ 29,273,635
US corporate debt securities	Less than 2	23,839,606	70	(37,337)	) 23,802,339
Total investments		\$53,327,364	\$ 2,737	\$ (254,127)	) \$ 53,075,974

#### 6. Marketable Securities and Fair Value Measurements

The guidance regarding fair value measurements establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets that are accessible at the measurement date; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any transfer of assets and liabilities between Level 1, Level 2 and Level 3 of the fair value hierarchy during the nine months ended September 30, 2015 or 2014.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis, and are determined using the following inputs as of September 30, 2015:

	Fair Value Measurements at September 30, 2015			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds	\$53,090,572	\$53,090,572	\$—	\$—
Mutual funds	58,235,334	—	58,235,334	—
US corporate debt securities	26,975,079	—	26,975,079	—
Municipal bonds	103,143	—	103,143	—
Investments in affiliated entities	25,321,361	25,321,361	—	—
Common stock warrants	88,900	—	—	88,900
Total Assets	\$163,814,389	\$78,411,933	\$85,313,556	\$88,900
<b>Liabilities:</b>				
Common stock warrants	\$1,093,752	\$—	\$—	1,093,752

Total Liabilities	\$1,093,752	\$—	\$—	\$1,093,752
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The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis, and are determined using the following inputs as of December 31, 2014:

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	Fair Value Measurements at December 31, 2014			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds	\$36,474,066	\$36,474,066	\$—	\$—
Mutual funds	29,273,635	—	29,273,635	—
US corporate debt securities	23,802,339	—	23,802,339	—
Investment in affiliated entity	12,340,811	12,340,811	—	—
Common stock warrants	550,000	—	—	550,000
<b>Total Assets</b>	<b>\$102,440,851</b>	<b>\$48,814,877</b>	<b>\$53,075,974</b>	<b>\$550,000</b>
<b>Liabilities:</b>				
Common stock warrants	\$2,022,729	\$—	\$—	\$2,022,729
<b>Total Liabilities</b>	<b>\$2,022,729</b>	<b>\$—</b>	<b>\$—</b>	<b>\$2,022,729</b>

Level 1 assets include money market funds held by the Company that are valued at quoted market prices, as well as the Company's investments in GeneOne and PLS. The Company accounts for its investment in GeneOne at fair value on a recurring basis by which the fair value is based on the market value of 1,644,155 common shares on September 30, 2015 and December 31, 2014, listed on the Korean Stock Exchange. The Company accounts for its investment in PLS as an available-for sale security by which the fair value is based on the market value of 395,758 common shares on September 30, 2015, listed on the Korea New Exchange (KONEX) Market. The Company elected the fair value option in conjunction with the investment in GeneOne at the inception of the investment therefore changes in the fair value of the investment are reflected as other income (expense) in the condensed consolidated statements of operations. The Company did not elect the fair value option for the investment in PLS at the inception of the investment, but rather recorded the investment under the equity method until its ownership interest dropped below 20% in June 2015 and accordingly began recording the investment under the cost method using the carryover basis from the equity method of zero. Once shares of PLS began trading on the KONEX, the Company classified the investment as available-for-sale and began recording the investment at fair value with changes in fair value reflected in other comprehensive income (loss).

Level 2 assets at September 30, 2015 include US corporate debt securities, mutual funds and municipal bonds held by the Company that are initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing market observable data. The Company obtains the fair value of its Level 2 assets from a professional pricing service, which may use quoted market prices for identical or comparable instruments, or inputs other than quoted prices that are observable either directly or indirectly. The professional pricing service gathers quoted market prices and observable inputs from a variety of industry data providers. The valuation techniques used to measure the fair value of the Company's Level 2 financial instruments were derived from non-binding market consensus prices that are corroborated by observable market data, quoted market prices for similar instruments, or pricing models such as discounted cash flow techniques. The Company validates the quoted market prices provided by the primary pricing service by comparing their assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source.

Level 3 assets at September 30, 2015 include two warrants received by the Company to purchase shares of common stock of OncoSec Medical Incorporated ("OncoSec"), in connection with the first and second amendments to the Asset Purchase Agreement between the Company and OncoSec signed in September 2011 and March 2012, respectively. The first warrant to purchase 50,000 shares of common stock of OncoSec has a contractual life of five years with an exercise price of \$24.00 per share. The second warrant to purchase 150,000 shares of common stock of OncoSec has a contractual life of five years with an exercise price of \$20.00 per share.

As of September 30, 2015 the Company has a long-term asset of \$89,000 associated with the warrants received to purchase common stock of OncoSec. The Company reassesses the fair value of the warrants at each reporting date



utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of OncoSec stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on publicly available historical data and knowledge of OncoSec. The Company reassesses the fair value of the warrants at each reporting date. The assumptions used to estimate the fair values of the OncoSec common stock warrants at September 30, 2015 are presented below:

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Risk-free interest rate	0.33-0.49%
Expected volatility	90%
Expected life in years	1.0-1.5
Dividend yield	—

As a result of these calculations, the Company recorded a decrease in fair value of the two warrants of \$98,000 and \$461,000 for the three and nine months ended September 30, 2015, respectively, and a decrease in fair value of the two warrants of \$290,000 and \$127,000 for the three and nine months ended September 30, 2014, respectively. The change in fair value is reflected in the Company's condensed consolidated statements of operations as a component of change in fair value of common stock warrants.

The following table presents a summary of changes in fair value of the Company's total Level 3 financial assets for the nine months ended September 30, 2015:

Balance at January 1, 2015	\$550,000
Decrease in fair value included in change in fair value of common stock warrants	(461,100 )
Balance at September 30, 2015	\$88,900

Level 3 liabilities held as of September 30, 2015 consist of common stock warrant liabilities associated with warrants to purchase the Company's common stock issued in March 2013. If unexercised, the warrants will expire in September 2018. During the three and nine months ended September 30, 2015, no warrants were exercised. During the three and nine months ended September 30, 2014, warrants to purchase 97,865 and 2,169,342 shares of common stock were exercised, respectively.

As of September 30, 2015 the Company has a \$1.1 million common stock warrant liability. The Company reassesses the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on historical data. The assumptions used to estimate the fair value of common stock warrants at September 30, 2015 are presented below:

Risk-free interest rate	0.92%
Expected volatility	83%
Expected life in years	3.0
Dividend yield	—

Changes in these assumptions as well as in the Company's stock price on the valuation date can have a significant impact on the fair value of the common stock warrant liability. As a result of these calculations, the Company recorded a decrease in fair value of \$616,000 and \$929,000 for the three and nine months ended September 30, 2015, respectively, and a decrease in fair value of \$176,000 and \$331,000 for the three and nine months ended September 30, 2014, respectively. The change in fair value is reflected in the Company's condensed consolidated statements of operations as a component of change in fair value of common stock warrants. Warrants that were exercised during the period were revalued on the day prior to exercise and then reclassified into stockholders' equity upon exercise.

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the nine months ended September 30, 2015:

Balance at January 1, 2015	\$2,022,729
Decrease in fair value included in change in fair value of common stock warrants	(928,977 )
Balance at September 30, 2015	\$1,093,752

## 7. Goodwill and Intangible Assets

The following sets forth the goodwill and intangible assets by major asset class:



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	Useful Life (Yrs)	September 30, 2015			December 31, 2014		
		Gross	Accumulated Amortization	Net Book Value	Gross	Accumulated Amortization	Net Book Value
<b>Non-Amortizing:</b>							
Goodwill(a)		\$ 10,113,371	\$—	\$ 10,113,371	\$ 10,113,371	\$—	\$ 10,113,371
<b>Amortizing:</b>							
Patents	8 – 17	5,802,528	(5,482,100 )	320,428	5,802,528	(5,358,433 )	444,095
Licenses	8 – 17	1,323,761	(1,125,926 )	197,835	1,323,761	(1,104,366 )	219,395
CELLECTRA®(b)	5 – 11	8,106,270	(6,291,176 )	1,815,094	8,106,270	(5,970,866 )	2,135,404
GHRH(b)	11	335,314	(200,661 )	134,653	335,314	(176,899 )	158,415
Other(c)	18	4,050,000	(2,400,000 )	1,650,000	4,050,000	(2,231,250 )	1,818,750
Total intangible assets		19,617,873	(15,499,863 )	4,118,010	19,617,873	(14,841,814 )	4,776,059
Total goodwill and intangible assets		\$ 29,731,244	\$(15,499,863)	\$ 14,231,381	\$ 29,731,244	\$(14,841,814)	\$ 14,889,430

(a) Goodwill was recorded from the Inovio AS acquisition in January 2005 and from the acquisition of VGX in June 2009 for \$3.9 million and \$6.2 million, respectively.

(b) CELLECTRA® and GHRH are developed technologies which were recorded from the acquisition of VGX.

(c) Other intangible assets represent the fair value of acquired intellectual property from the Inovio AS acquisition. Aggregate amortization expense on intangible assets for the three and nine months ended September 30, 2015 was \$215,000 and \$658,000, respectively. Aggregate amortization expense on intangible assets for the three and nine months ended September 30, 2014 was \$235,000 and \$712,000, respectively. Estimated aggregate amortization expense for each of the five succeeding fiscal years is \$212,000 for the remainder of fiscal year 2015, \$816,000 for 2016, \$775,000 for 2017, \$773,000 for 2018, \$773,000 for 2019 and \$769,000 for 2020 and the years thereafter.

## 8. Stockholders' Equity

The following is a summary of the Company's authorized and issued common and preferred stock as of September 30, 2015 and December 31, 2014:

	Authorized	Issued	Outstanding as of September 30, 2015	December 31, 2014
Common Stock, par \$0.001	600,000,000	72,180,794	72,180,794	60,741,082
Series A Preferred Stock, par \$0.001	1,000	817	—	—
Series B Preferred Stock, par \$0.001	1,000	750	—	—
Series C Preferred Stock, par \$0.001	1,091	1,091	23	23
Series D Preferred Stock, par \$0.001	1,966,292	1,966,292	—	—

### Common Stock

On May 5, 2015, the Company closed an underwritten public offering of 10,925,000 shares of the Company's common stock, including 1,425,000 shares of common stock issued pursuant to the underwriter's exercise of its overallotment option, at the public offering price of \$8.00 per share. The net proceeds, after deducting the underwriter's discounts and commission and other estimated offering expenses, were approximately \$81.9 million. In March 2014, the Company closed an underwritten public offering of 5,452,725 shares of the Company's common stock, including 711,225 shares of common stock issued pursuant to the underwriter's exercise of its overallotment option, at the public offering price of \$11.60 per share. The net proceeds, after deducting the underwriter's discounts and commission and other estimated offering expenses, were approximately \$59.2 million.

In March 2013, the Company completed an underwritten offering of 6,844,317 shares of common stock and warrants to



purchase an aggregate of up to 3,422,158 shares of common stock. The shares and warrants were sold in units at a price of \$2.20 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.50 share of common stock at an exercise price of \$3.1744 per share. The warrants have a term of 5.5 years. The net proceeds, after deducting the underwriters' discounts and other offering expenses, were approximately \$14.0 million. The Company valued the registered warrants issued in connection with the March 2013 financing as of the issuance date using the Black Scholes pricing model and recorded a current liability on the condensed consolidated balance sheet. As of September 30, 2015, 3,138,067 of these warrants had been exercised.

The Company accounts for registered common stock warrants issued in March 2013 under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. The Company classifies registered warrants on the condensed consolidated balance sheet as a current liability which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The Company develops its estimates based on historical data. A small change in the estimates used may have a relatively large change in the estimated valuation. The Company uses the Black-Scholes pricing model to value the registered warrants. Changes in the fair market value of the warrants are reflected in the condensed consolidated statement of operations as "Change in fair value of common stock warrants."

#### Warrants

The following table summarizes the warrants outstanding as of September 30, 2015 and December 31, 2014:

Issued in Connection With:	Exercise Price	Expiration Date	As of September 30, 2015		As of December 31, 2014	
			Number of Warrants	Common Stock Warrant Liability	Number of Warrants	Common Stock Warrant Liability
March 2013 financing	\$3.17	September 12, 2018	284,091	\$ 1,093,752	284,091	\$ 2,022,729
Warrants assumed in June 2009 Merger	\$4.08-\$5.08	April 28, 2016	296,813	—	727,969	—
Total			580,904	\$ 1,093,752	1,012,060	\$ 2,022,729

#### Stock Options

The Company has one active stock-based incentive plan, the Amended and Restated 2007 Omnibus Incentive Plan (the "Incentive Plan"), pursuant to which the Company has granted stock options and restricted stock awards to executive officers, directors and employees. The Incentive Plan was adopted on March 31, 2007, approved by the stockholders on May 4, 2007, approved by the stockholders as amended on May 2, 2008, and approved by the stockholders as amended and restated on August 25, 2009, May 14, 2010, May 22, 2014 and May 8, 2015. On May 14, 2010 the stockholders approved to increase the aggregate number of shares available for grant under the Incentive Plan by 500,000 and to provide that the aggregate number of shares available for grant under the Incentive Plan will be increased on January 1 of each year beginning in 2011 by a number of shares equal to the lesser of 513,833 or such lesser number of shares as may be determined by the Board. On May 22, 2014 and May 8, 2015, the stockholders approved to increase the aggregate number of shares available for grant under the Incentive Plan by 1,250,000 and 2,000,000, respectively. At September 30, 2015, there were 6,729,052 shares of common stock reserved for issuance upon exercise of incentive awards granted and to be granted at future dates under the Incentive Plan. At September 30, 2015, the Company had 2,032,801 shares of common stock available for future grant under the Incentive Plan, 230,000 shares of unvested restricted stock units and options to purchase 4,466,251 shares of common stock outstanding under the Incentive Plan. The awards granted and available for future grant under the Incentive Plan generally vest over three years and have a maximum contractual term of ten years. The Incentive Plan terminates by its terms on March 31, 2017.

The Incentive Plan supersedes all of the Company's previous stock option plans, which include the Amended 2000 Stock Option Plan and the VGX Equity Compensation Plan, under which the Company had options to purchase

148,878 and 1,260,082 shares of common stock outstanding at September 30, 2015, respectively. The terms and conditions of the options outstanding under these plans remain unchanged.

## 9. Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing the net income (loss) for the year by the weighted average number of common shares outstanding during the year. Diluted income (loss) per share is calculated in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. The calculation of diluted income (loss) per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to loss per share for the period, an adjustment to net loss used in the calculation is required to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

The following tables reconcile the components of the numerator and denominator included in the calculations of diluted income (loss) per share:

	Three Months Ended September 30,	
	2015	2014
Numerator		
Net income (loss) attributable to Inovio Pharmaceuticals, Inc.	\$5,594,468	\$(7,177,575)
Reflect adjustment for decrease in fair value of warrant liability	(616,477)	) (271,022)
Numerator for use in diluted income (loss) per share	\$4,977,991	\$(7,448,597)
Denominator		
Weighted average number of common shares outstanding	72,029,644	60,392,911
Effect of dilutive potential common shares	1,931,593	209,920
Denominator for use in diluted income (loss) per share	73,961,237	60,602,831
Net income (loss) per share, diluted	\$0.07	\$(0.12)
	Nine Months Ended September 30,	
	2015	2014
Numerator		
Net loss attributable to Inovio Pharmaceuticals, Inc.	\$(11,235,561)	) \$(28,710,309)
Reflect adjustment for decrease in fair value of warrant liability	(928,978)	) (1,996,544)
Numerator for use in diluted loss per share	\$(12,164,539)	) \$(30,706,853)
Denominator		
Weighted average number of common shares outstanding	66,846,481	58,625,740
Effect of dilutive potential common shares	172,480	310,674
Denominator for use in diluted loss per share	67,018,961	58,936,414
Net loss per share, diluted	\$(0.18)	) \$(0.52)



The following table summarizes potential common shares that were excluded from the diluted net income (loss) per share calculation because of their anti-dilutive effect for the three months ended September 30, 2015:

Common Stock Equivalents	2015	2014
Options to purchase common stock	2,812,185	4,833,877
Warrants to purchase common stock	—	978,052
Convertible preferred stock	8,456	8,456
Total	2,820,641	5,820,385

The following table summarizes potential common shares that were excluded from the diluted net loss per share calculation because of their anti-dilutive effect for the nine months ended September 30, 2015:

Common Stock Equivalents	2015	2014
Options to purchase common stock	5,875,211	4,833,877
Warrants to purchase common stock	580,904	978,052
Restricted stock units	230,000	—
Convertible preferred stock	8,456	8,456
Total	6,694,571	5,820,385

#### 10. Stock-Based Compensation

The Company incurs stock-based compensation expense related to restricted stock units and stock options. The fair value of restricted stock is determined by the closing market price of the Company's common stock on the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility and expected option life. The Company amortizes the fair value of the awards expected to vest on a straight-line basis over the requisite service period of the awards. Expected volatility is based on historical volatility. The expected life of options granted is based on historical expected life. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant. The forfeiture rate is based on historical data, and the Company records stock-based compensation expense only for those awards that are expected to vest. The dividend yield is based on the fact that no dividends have been paid historically and none are currently expected to be paid in the foreseeable future.

The weighted average assumptions used in the Black-Scholes model for employees and directors are presented below:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.05%	0.93%	0.99%	1.49%
Expected volatility	75%	79%	74%	110%
Expected life in years	5.0	5.0	5.0	5.1
Dividend yield	—	—	—	—
Forfeiture rate	7%	8%	7%	8%

Total employee and director compensation cost for the Company's stock plan recognized in the condensed consolidated statement of operations for the three and nine months ended September 30, 2015 was \$1.1 million and \$4.6 million, respectively, of which \$565,000 and \$2.6 million were included in research and development expenses and \$559,000 and \$2.0 million were included in general and administrative expenses, respectively.

Total employee and director compensation cost for the Company's stock plan recognized in the condensed consolidated statement of operations for the three and nine months ended September 30, 2014 was \$708,000 and \$4.0 million, respectively,



of which \$410,000 and \$2.4 million were included in research and development expenses and \$298,000 and \$1.6 million were included in general and administrative expenses, respectively.

At September 30, 2015, there was \$8.2 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.0 years.

The weighted average grant date fair value per share was \$4.59 and \$4.62 for employee and director stock options granted during the three and nine months ended September 30, 2015, respectively, and \$6.51 and \$9.32 for employee and director stock options granted during the three and nine months ended September 30, 2014, respectively.

At September 30, 2015, there was \$1.4 million of total unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.3 years.

The weighted average grant date fair value was \$7.76 per share for employee restricted stock units granted during the nine months ended September 30, 2015. There were no restricted stock units granted during the three months ended September 30, 2015 and no restricted stock units granted during the three and nine months ended September 30, 2014.

The fair value of options granted to non-employees at the measurement dates were estimated using the Black-Scholes pricing model. Total stock-based compensation for options granted to non-employees for the three and nine months ended September 30, 2015 was \$3,000 and \$273,000, respectively. Total stock-based compensation for options granted to non-employees for the three and nine months ended September 30, 2014 was \$88,000 and \$547,000, respectively.

## 11. Related Party Transactions

### GeneOne Life Sciences

On May 26, 2015, the Company entered into a Collaborative Development Agreement with GeneOne to co-develop a DNA vaccine for MERS (Middle East Respiratory Syndrome) through phase I clinical trials.

On September 23, 2014, the Company entered into a Collaborative Development Agreement with GeneOne to co-develop an Ebola vaccine through phase I clinical trials. In July 2015, the Company amended the Agreement with an effective date of April 2015 to change control of development in return for the Company's payment of certain development fees.

On October 7, 2011, the Company entered into a Collaborative Development and License Agreement (the "Hep Agreement") with GeneOne. Under the Hep Agreement, as originally executed, the Company and GeneOne agreed to co-develop the Company's SynCor<sup>®</sup> therapeutic vaccines for hepatitis B and C infections (the "Products"). Under the terms of the Hep Agreement, GeneOne will receive marketing rights for the Products in Asia, excluding Japan, and in return will fully fund IND-enabling and initial Phase I and II clinical studies with respect to the Products. The Company will receive from GeneOne payments based on the achievement of clinical milestones and royalties based on sales of the Products in the licensed territories, retaining all commercial rights to the Products in all other territories. On August 21, 2013, the Company amended the Hep Agreement to grant back to the Company hepatitis B, along with all associated rights, from the collaboration in return for certain remuneration including a percentage of license fees. On October 7, 2013, the Company further amended the Hep Agreement to in part provide exclusive patent rights to IL-28 technology for use with the Products in Asia, excluding Japan.

On March 24, 2010, the Company entered into a Collaboration and License Agreement (the "GeneOne Agreement") with GeneOne. Under the GeneOne Agreement, the Company granted GeneOne an exclusive license to Inovio's SynCon<sup>®</sup> universal influenza vaccine delivered with electroporation to be developed in certain countries in Asia (the "Product"). As consideration for the license granted to GeneOne, the Company received payment of \$3.0 million, and will receive research support, annual license maintenance fees and royalties on net Product sales. The Company recorded the \$3.0 million as deferred revenue from affiliated entity, and will recognize it as revenue over the eight year expected period of the Company's performance obligation. In addition, contingent upon achievement of clinical and regulatory milestones, the Company will receive development payments over the term of the GeneOne Agreement. The GeneOne Agreement also provides Inovio with exclusive rights to supply devices for clinical and commercial purposes (including single use components) to GeneOne for use in the Product. The term of the GeneOne Agreement commenced upon execution and will extend on a country by country basis until the last to expire of all Royalty Periods for the territory (as such term is defined in the GeneOne Agreement) for any Product in that country, unless the GeneOne Agreement is terminated earlier in accordance with its provisions as a result of breach, by mutual

agreement, or by GeneOne's right to terminate without cause upon prior written notice.

For the three and nine months ended September 30, 2015, the Company recognized revenue from GeneOne of \$113,000 and \$338,000, respectively, which consisted of licensing and other fees. Operating expenses related to GeneOne for the three and nine months ended September 30, 2015 include \$1.1 million and \$6.5 million, respectively, related to biologics manufacturing. For the three and nine months ended September 30, 2014, the Company recognized revenue from GeneOne of \$113,000 and \$367,000, respectively, which consisted of licensing and other fees. Operating expenses related to GeneOne for the three and nine months ended September 30, 2014 include \$413,000 and \$4.1 million, respectively, related to biologics

manufacturing. At September 30, 2015 and December 31, 2014, the Company had an accounts receivable balance of \$0 and \$2,000, respectively, and an accounts payable and accrued liability balance of \$2.8 million and \$28,000, respectively, related to GeneOne and its subsidiaries. At September 30, 2015 and December 31, 2014, \$213,000 and \$260,000 of prepayments made to GeneOne were classified as long-term other assets on the consolidated balance sheet, respectively.

#### OncoSec Medical Incorporated

The Company's non-executive Chairman, Dr. Avtar Dhillon, is also the non-executive Chairman of OncoSec.

On September 28, 2011, the Company signed an amended agreement with OncoSec extending the term of the second payment owed to the Company in exchange for a warrant to purchase 50,000 shares of common stock of OncoSec. The warrant received was a five-year warrant with an exercise price of \$24.00 per share. (See Note 6 for further discussion.)

On March 24, 2012, the Company signed a second amended agreement with OncoSec further extending the term of the payments owed to the Company in exchange for a warrant to purchase 150,000 shares of common stock of OncoSec. The warrant received was a five-year warrant with an exercise price of \$20.00 per share. (See Note 6 for further discussion.)

#### Plumblin Life Sciences, Inc.

In May 2014, the Company's 85% owned subsidiary VGX Animal Health entered into an agreement for the sale of its animal health assets to Plumblin Life Sciences, Inc. ("PLS") of Korea. The assets transferred included an exclusive license with Inovio for animal applications of its growth hormone-releasing hormone ("GHRH") technology and animal DNA vaccines plus a non-exclusive license to Inovio electroporation delivery systems. In May 2015, VGX Animal Health received payment of \$1.0 million from PLS and is scheduled to receive an additional \$1.0 million payment in 2016. No receivable has been recorded for the \$1.0 million due from PLS as collection is uncertain. VGX Animal Health received 20% of the outstanding shares of PLS and received additional shares to maintain its 20% equity ownership position in PLS until equity fund-raising by PLS reached \$10.0 million in June 2015. In July 2015 the Company's ownership in VGX Animal Health decreased from 91% to 85%. After the Company's ownership changed, VGX Animal Health distributed its 465,364 shares of PLS to its shareholders in a pro-rata distribution. After the distribution, the Company held 395,758 shares, or approximately 16.9% of PLS common stock.

As of September 30, 2015 the Company accounts for its ownership interest in PLS under the accounting guidance for investments considered available-for-sale (Accounting Standards Codification (ASC) 320). The original carrying value of the Company's investment in PLS was \$0. On July 28, 2015, PLS registered on the Korea New Exchange (KONEX) Market. The total carrying value of the Company's investment in PLS was \$7.1 million as of September 30, 2015. The fair value is based on the market value of the 395,758 common shares owned, listed on the KONEX. The changes in carrying value of PLS are recorded in the condensed consolidated statements of comprehensive income (loss) as an unrealized gain on investment in affiliated entity.

#### 12. Commitments and Contingencies

In March 2014, the Company entered into an office lease (the "Lease") with a publicly owned real estate investment trust, located in Plymouth Meeting, Pennsylvania. The Company occupied the new space in June 2014. The initial term of the Lease is 11.5 years and the Company plans to use the facility for office purposes.

The base rent adjusts periodically throughout the 11.5 year term of the Lease, with monthly payments ranging from \$0 to \$58,000. In addition, the Company will pay the landlord its share of operating expenses and a property management fee and has paid a security deposit of \$49,000. The Company has capitalized \$933,000 of tenant improvements within fixed assets on the condensed consolidated balance sheet and has recorded a corresponding increase to deferred rent. In July 2015, the Company amended the lease for its headquarters in Plymouth Meeting, Pennsylvania to increase the total leased space. The commencement of the amended lease is estimated to be in the first quarter of 2016 and will increase monthly lease payments by approximately \$16,000.

In August 2015 the Company entered into a sublease for its previous facility and completely vacated the premises. The Company has recorded a cease-use accrual of \$80,000 as of September 30, 2015.

In June 2015, the Company amended the lease for its corporate office in San Diego, California to increase the total leased space and occupy the entire building. The amendment requires the lessor to complete and pay for certain improvements to the additional space before the commencement of the amended lease which is estimated to be in the fourth quarter of 2015. The amended lease will increase monthly lease payments by approximately \$13,000. The Company has capitalized \$187,000

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of tenant improvements within fixed assets on the condensed consolidated balance sheet related to this additional space, and has recorded a corresponding increase to deferred rent.

The Company's future minimum lease payments under all non-cancelable operating leases as of September 30, 2015 are as follows:

Remainder of 2015	\$201,000
2016	1,573,000
2017	1,684,000
2018	1,655,000
2019	1,884,000
2020	1,932,000
Thereafter	9,732,000
Total	\$18,661,000

In the normal course of business, the Company is a party to a variety of agreements pursuant to which they may be obligated to indemnify the other party. It is not possible to predict the maximum potential amount of future payments under these types of agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement. Historically, payments made by us under these types of agreements have not had a material effect on our business, consolidated results of operations or financial condition.

### 13. Collaborative Agreements

#### MedImmune

On August 7, 2015, The Company entered into a license and collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca. Under the agreement, MedImmune acquired exclusive rights to the Company's INO-3112 immunotherapy, which targets cancers caused by human papillomavirus (HPV) types 16 and 18. MedImmune made an upfront payment of \$27.5 million to the Company in September 2015 and has agreed to make additional future development, regulatory and commercial event based payments totaling up to \$700 million. MedImmune will fund all development costs associated with INO-3112 immunotherapy. The Company is entitled to receive up to mid-single to double-digit tiered royalties on INO-3112 product sales. Within the broader collaboration, the Company and MedImmune will develop up to two additional DNA-based cancer vaccine products not included in the Company's current product pipeline, which MedImmune will have the exclusive rights to develop and commercialize. The Company will receive development, regulatory and commercialization event based payments and will be eligible to receive royalties on worldwide net sales for these additional cancer vaccine products. The Company has assessed event based payments under the authoritative guidance for research and development milestones and determined that none of the event based payments represent a milestone under the milestone method of accounting. The Company identified the deliverables at the inception of the agreement. The Company has determined that the license to INO-3112, the license for the research collaboration products with related research and development services and the product development services for INO-3112 individually represent separate units of accounting because each deliverable has standalone value. The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value and thus should be treated as separate units of accounting. The Company determined that the license for INO-3112, the license for the research collaboration products with related research and development services, and the product development services for INO-3112 have standalone value and represent separate units of accounting because the rights conveyed permit MedImmune to perform all efforts necessary to complete development, commercialize and begin selling the product upon regulatory approval. In addition, MedImmune has the appropriate development, regulatory and commercial expertise with products similar to the product licensed under the agreement and has the ability to engage third parties to manufacture the product allowing MedImmune to realize the value of the license without receiving any of the remaining deliverables. MedImmune can also sublicense its license rights to third parties. Also, the Company determined that the product development services for INO-3112 represents an individual unit of accounting as

MedImmune could perform such services and/or could acquire these on a separate basis. The best estimated selling prices for these units of accounting were determined based on market conditions, the terms of comparable collaborative agreements for similar technology in the pharmaceutical and biotechnology industry, the Company's pricing practices and pricing objectives and the nature of the research and development services to be provided. While market data and the cost-to-recreate method under the cost approach were considered throughout the valuation process, ultimately, the estimated selling prices of the



licenses were determined utilizing two forms of the relief from royalty method under the income approach. The arrangement consideration was allocated to the deliverables based on the relative selling price method.

The amount allocable to the delivered unit or units of accounting is limited to the amount that is considered fixed and determinable and is not contingent upon the delivery of additional items or meeting other specified performance conditions. Based on the results of the Company's analysis, the \$27.5 million up-front payment was allocated as follows: \$15.0 million to the product license to INO-3112 and \$12.5 million for the license to the research collaboration products and related research and developments services. The amount allocated to the license for INO-3112 was recognized as revenue under collaborative research and development arrangements during the three months ended September 30, 2015 as this was determined to be earned upon the granting of the license and delivery of the related knowledge and data. The remaining amount related to the research collaboration products and related research and development services is classified as long-term deferred revenue as of September 30, 2015. The Company believes that no substantive value related to the research collaboration product license and research services has been transferred to MedImmune prior to their selection of the first research collaboration product since there is no economic benefit from the research unless such product candidate is selected. Furthermore, if MedImmune decides to not proceed with the selection of the product candidate, the research collaboration product license would be terminated. Therefore, the Company believes the license for the research collaboration products is not delivered until the research services are completed and the selection of the product candidate is made by MedImmune (i.e. exercise of an option). The Company has classified the amount allocated to this deliverable as long-term deferred revenue as it is not expected that MedImmune will select a product candidate within the next 12 months. As of September 30, 2015, the Company has a deferred revenue and accounts receivable balance of \$12.5 million and \$140,000 respectively, related to the Agreement.

Roche

In September 2013, the Company entered into a Collaborative, License, and Option Agreement (the "Agreement") with Roche. The companies agreed to co-develop multi-antigen DNA immunotherapies targeting prostate cancer and hepatitis B (the "Products").

On November 14, 2014, Roche provided notice that they would be partially terminating the Agreement with respect to the development of INO-5150, the Company's DNA immunotherapy targeting prostate cancer, as well as the research collaboration in prostate cancer under the Agreement. The termination was effective in February 2015, 90 days after the date of notice. All of Roche's rights to INO-5150, including the right to license the product to other parties, have been returned to the Company. The Company and Roche will continue to collaborate and co-develop the Company's DNA immunotherapy (INO-1800) against hepatitis B virus under the existing Agreement.

Under the original agreement, Roche acquired an exclusive worldwide license for the Company's DNA-based vaccines INO-5150 (targeting prostate cancer) and INO-1800 (targeting hepatitis B) as well as the use of the Company's CELLECTRA® electroporation technology for delivery of the vaccines. Roche also obtained an option to license additional vaccines in connection with a collaborative research program in prostate cancer.

Under the terms of the agreement, Roche made an upfront payment of \$10.0 million and agreed to make additional development, regulatory and commercial event based payments. These potential future event based payments have been reduced significantly due to the partial termination of the Agreement. The Company has assessed event based payments under the authoritative guidance for research and development milestones and determined that \$3.0 million related to INO-1800 represents a milestone under the milestone method of accounting.

The Company is entitled to receive up to mid-single to double-digit tiered royalties on product sales. Unless terminated earlier in accordance with its terms, the Agreement continues in effect until the date when no royalty or other payment obligations under the Agreement are or will become due, i.e., a royalty term ending on the later of the date that is (a) ten years after the date of the first commercial sale of the product that is subject to the agreement or (b) the expiration of the last to expire of the patent rights that are subject to the agreement. Under the terms of the agreement the Company also agreed to perform research and development services, which include preclinical and clinical costs, and manufacturing and supply services, at Roche's expense.

The Company identified the deliverables at the inception of the agreement. The Company has determined that the license to INO-5150 and INO-1800, the option right to license additional vaccines, research and development services, manufacturing and drug supply, and participation in the joint steering committee individually represent

separate units of accounting because each deliverable has standalone value. The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value and thus should be treated as separate units of accounting. The Company determined that the licenses and option right to license additional vaccines have standalone value and represent separate units of accounting because the rights conveyed permit Roche to perform all efforts necessary to complete development, commercialize and begin selling the product upon regulatory approval. In addition, Roche has the appropriate development, regulatory and commercial expertise with products similar to the product licensed under the agreement and has the ability to engage third parties to manufacture the product allowing Roche to realize the value of the

license without receiving any of the remaining deliverables. Roche can also sublicense its license rights to third parties. Also, the Company determined that the research services, committee participation and manufacturing services each represent individual units of accounting as Roche could perform such services and/or could acquire these on a separate basis. The best estimated selling prices for these units of accounting were determined based on market conditions, the terms of comparable collaborative agreements for similar technology in the pharmaceutical and biotechnology industry, the Company's pricing practices and pricing objectives and the nature of the research and development services to be provided. While market data and the cost-to-recreate method under the cost approach were considered throughout the valuation process, ultimately, the selling prices of the licenses and option right were determined utilizing two forms of the relief from royalty method under the income approach. The arrangement consideration was allocated to the deliverables based on the relative selling price method.

The amount allocable to the delivered unit or units of accounting is limited to the amount that is considered fixed and determinable and is not contingent upon the delivery of additional items or meeting other specified performance conditions. Based on the results of the Company's analysis, the \$10.0 million up-front payment was allocated as follows: \$5.0 million and \$3.4 million to the license to INO-5150 and INO-1800, respectively, \$1.5 million to the option right and \$155,000 to the joint steering committee obligation. The amounts allocated to the licenses for INO-5150 and INO-1800 were recognized as revenue under collaborative research and development arrangements during the year ended December 31, 2013 as these were determined to be earned upon the granting of the license and delivery of the related knowledge and data. Due to the Company's continuing involvement obligations, the remaining amounts were classified as deferred revenue as of December 31, 2013. The Company will recognize revenues associated with research and development services and manufacturing and drug supply as revenues under collaborative arrangements as the related services are performed and according to the relative selling price method of the allocable arrangement consideration. During the three and nine months ended September 30, 2015, the Company recognized revenues of \$1.3 million and \$9.9 million from Roche, respectively. Of the nine month period revenues, \$3.0 million related to previously deferred revenue which was recognized based on the partial termination of the Agreement in February 2015 and \$3.0 million related to a milestone earned during the period. As of September 30, 2015, the Company has a deferred revenue and accounts receivable balance of \$313,000 and \$3.0 million, respectively, related to the Agreement.

#### 14. Income Taxes

The Company uses an estimated annual effective tax rate, which is based on expected annual income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates, to determine its quarterly provision for income taxes. Certain significant or unusual items are separately recognized in the quarter in which they occur and can be a source of variability in the effective tax rates from quarter to quarter. The income tax benefit recorded during the three months ended September 30, 2015 of \$1.8 million is principally due to a requirement under Accounting Standards Codification (ASC) 740, Accounting for Income Taxes, that a Company must consider all sources of income in order to determine the tax benefit resulting from a loss from continuing operations. As a result of the requirement under ASC 740-20-45-7, the pretax income which the Company generated from other comprehensive income was a source of income which resulted in the partial realization of the current year loss from continuing operations. During the three and nine months ended September 30, 2015 the Company has recorded an approximate \$1.8 million tax benefit to continuing operations out of the full year benefit of \$3.1 million and an offsetting \$3.1 million charge to other comprehensive income.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report contains forward-looking statements, as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. We are under no obligation to update any of the forward-looking statements after the filing of this Quarterly Report to conform such statements to actual results or to changes in our expectations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this Quarterly Report. Readers are also urged to carefully review and consider the various disclosures made by us that attempt to advise interested parties of the factors that affect our business, including without limitation the disclosures made in Item 1A of Part II of this Quarterly Report under the Caption "Risk Factors" and under the captions "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Risk Factors" and in our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Risk factors that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to: our history of losses; our lack of products that have received regulatory approval; uncertainties inherent in clinical trials and product development programs, including but not limited to the fact that pre-clinical and clinical results may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve desired results, that pre-clinical studies and clinical trials may not commence, have sufficient enrollment or be completed in the time periods anticipated, that results from one study may not necessarily be reflected or supported by the results of other similar studies, that results from an animal study may not be indicative of results achievable in human studies, that clinical testing is expensive and can take many years to complete, that the outcome of any clinical trial is uncertain and failure can occur at any time during the clinical trial process, and that our electroporation technology and DNA vaccines may fail to show the desired safety and efficacy traits in clinical trials; the availability of funding; the ability to manufacture vaccine candidates; the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that we and our collaborators hope to develop; whether our proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity; and the impact of government healthcare proposals.

### General

We are developing active DNA immunotherapies and vaccines focused on treating and preventing cancers and infectious diseases. Our DNA-based immunotherapies, in combination with our proprietary electroporation delivery devices, are intended to generate robust immune responses, in particular T cells, to fight such diseases. In 2014 we reported that in a large, controlled phase II clinical study we achieved clinically relevant efficacy against a targeted disease (HPV-associated cervical dysplasia) by generating antigen-specific T cells. Our novel SynCon<sup>®</sup> immunotherapy design has shown the ability to help break the immune system's tolerance of cancerous cells. Alternatively, our SynCon<sup>®</sup> product design is also intended to facilitate cross-strain protection against known as well as new unmatched strains of pathogens such as influenza. Given the recognized role of killer T cells in eliminating cancerous or infected cells from the body, our scientists believe that our active immunotherapies may play an important role in helping fight such diseases. Human data to date have shown a favorable safety profile of our DNA immunotherapies delivered using electroporation.

We have completed, current or planned clinical programs of our proprietary SynCon<sup>®</sup> immunotherapies for HPV-caused pre-cancers and cancers, prostate cancer, breast/lung/pancreatic cancer, hepatitis C virus (HCV), hepatitis B virus (HBV), HIV, influenza, and Ebola. Our partners and collaborators include F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (“Roche”), University of Pennsylvania, Drexel University, National Microbiology Laboratory of the Public Health Agency of Canada, , National Institute of Allergy and Infectious Diseases (“NIAID”), United States Military HIV Research Program (“USMHRP”), U.S. Army Medical Research Institute of Infectious Diseases (“USAMRIID”), HIV Vaccines Trial Network (“HVTN”), Defense Advanced Research Projects Agency (“DARPA”) and MedImmune, LLC.

All of our potential human products are in research and development phases. We have not generated any revenues from the sale of any such products, and we do not expect to generate any such revenues for at least the next several years. We earn

revenue from license fees and milestone revenue, collaborative research and development agreements, grants and government contracts. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that we advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. We may not be successful in our research and development efforts, and we may never generate sufficient product revenue to be profitable.

#### Recent Developments

On August 7, 2015, we entered into a license and collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca. Under the agreement, MedImmune acquired exclusive rights to our INO-3112 immunotherapy, which targets cancers caused by human papillomavirus (HPV) types 16 and 18.

MedImmune has made an upfront payment of \$27.5 million and will make potential future payments upon reaching development and commercial milestones totaling up to \$700 million. MedImmune will fund all development costs.

We are entitled to receive up to double-digit tiered royalties on INO-3112 product sales. Within the broader collaboration, we will develop with MedImmune up to 2 additional DNA-based cancer vaccine products not included in our current product pipeline, which MedImmune will have the exclusive rights to develop and commercialize if they so choose. We will receive development, regulatory and commercialization event based payments and will be eligible to receive royalties on worldwide net sales for these additional cancer vaccine products.

On May 5, 2015, we closed an underwritten public offering of 10,925,000 shares of our common stock, including 1,425,000 shares of common stock issued pursuant to the underwriter's exercise of its overallotment option, at the public offering price of \$8.00 per share. The net proceeds, after deducting the underwriter's discounts and commission and other offering expenses, were \$81.9 million.

As of September 30, 2015 we had an accumulated deficit of \$343.1 million. We expect to continue to incur substantial operating losses in the future due to our commitment to our research and development programs, the funding of preclinical studies, clinical trials and regulatory activities and the costs of general and administrative activities.

#### Critical Accounting Policies

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and require management's judgment. Our discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with U.S. GAAP. There have been no changes to our critical accounting policies during the three and nine months ended September 30, 2015. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. We base our estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. Our critical accounting policies include:

##### Revenue Recognition.

###### Grant revenue

We receive non-refundable grants under available government programs. Government grants towards current expenditures are recorded as revenue when there is reasonable assurance that we have complied with all conditions necessary to receive the grants, collectability is reasonably assured, and as the expenditures are incurred.

###### License fee and milestone revenue

We have adopted a strategy of co-developing or licensing our gene delivery technology for specific genes or specific medical indications. Accordingly, we have entered into collaborative research and development agreements and have received funding for pre-clinical research and clinical trials. Prior to the adoption of the Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") No. 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements, we analyzed our multiple element arrangements to determine whether the identified deliverables could be accounted for individually as separate units of accounting. The delivered item(s) were considered a separate unit of accounting if all of the following criteria were met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the

undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If these criteria were not met, the deliverable was combined with other deliverables in the arrangement and accounted for as a combined unit of accounting.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements,

we identify the deliverables included within the agreement and evaluate which deliverables represent separable units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (“VSOE”), of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the collaborator is fixed or determinable, and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

Prior to the adoption of ASU No. 2010-17, Revenue Recognition (Topic 605): Milestone Method of Revenue Recognition (“Milestone Method”), we recognized non-refundable milestone payments upon the achievement of specified milestones upon which we had earned the milestone payment, provided the milestone payment was substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement. We deferred payments for milestone events that were reasonably assured and recognized them ratably over the minimum remaining period of our performance obligations. Payments for milestones that were not reasonably assured were treated as the culmination of a separate earnings process and were recognized as revenue when the milestones were achieved.

Effective January 1, 2011, we adopted on a prospective basis the Milestone Method of ASU No. 2010-17. Under the Milestone Method, we will recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement
1. of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone,
  2. The consideration relates solely to past performance, and
  3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

**Research and Development Expenses.** Since our inception, most of our activities have consisted of research and development efforts related to developing our electroporation technologies and DNA vaccines. Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred. These expenses result from our independent research and development efforts as well as efforts associated with collaborations and licensing arrangements. We review and accrue clinical trials expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can



be made. Accrued clinical costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development expense; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Stock-based Compensation. We have equity incentive plans under which we have granted incentive stock options, restricted stock units and non-qualified stock options. We are required to measure and recognize compensation expense for all

share-based payments based on estimated fair value. The fair value of our restricted stock units is based on the market price of our common stock on the date of grant.

Our employee stock-based compensation cost is estimated at the grant date based on the fair-value of the award and is recognized as an expense ratably over the requisite service period of the award. Determining the appropriate fair-value model and calculating the fair value of stock-based awards at the grant date requires considerable judgment, including estimating stock price volatility, expected option life and forfeiture rates. We develop our estimates based on historical data. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value stock option awards. We recognize compensation expense using the straight-line amortization method. Our non-employee stock-based compensation awards are measured at either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured at each reporting date using the stock price and other measurement assumptions as of the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (ii) the date at which the counterparty's performance is completed.

#### Adoption of Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is contained in Note 3 to the Condensed Consolidated Financial Statements, included elsewhere in this report.

#### Results of Operations

**Revenue.** We had total revenue of \$24.2 million and \$34.6 million for the three and nine months ended September 30, 2015, respectively, as compared to \$1.8 million and \$8.0 million for the three and nine months ended September 30, 2014, respectively. Revenue primarily consists of revenue under collaborative research and development arrangements, grants and government contracts.

Revenue under collaborative research and development arrangements, including arrangements with affiliated entities, was \$16.6 million and \$25.5 million for the three and nine months ended September 30, 2015, respectively, as compared to \$1.2 million and \$6.0 million for the three and nine months ended September 30, 2014, respectively. The increase for the three-month period year over year was primarily due to the revenue recognized from our Agreement with MedImmune entered into in August 2015 (see Note 13). The increase for the nine-month period year over year was primarily due to the revenue recognized from our Agreement with MedImmune and revenue recognized from the Roche Agreement which was previously deferred related to the partial termination of the Agreement as well as the \$3.0 million milestone earned during the period.

During the three and nine months ended September 30, 2015, we recorded grant and miscellaneous revenue of \$7.6 million and \$9.2 million, respectively, as compared to \$613,000 and \$2.0 million for the three and nine months ended September 30, 2014, respectively. The increase for the three and nine-month periods year over year was primarily due to revenue recognized from our DARPA Ebola grant of \$7.3 million, offset by less revenue recognized from various grants due to the timing of work performed.

**Research and Development expenses.** Research and development expenses for the three and nine months ended September 30, 2015, were \$16.1 million and \$42.2 million, respectively, as compared to \$7.0 million and \$24.9 million for the three and nine months ended September 30, 2014, respectively. The increase for the three-month period year over year was primarily due to an increase in clinical study costs, sub-license fee expense based on the up-front payment received from MedImmune, increased employee headcount to support clinical trials and partnerships and an increase in expenses related to our DARPA Ebola grant of \$3.0 million, \$2.0 million, \$1.6 million and \$923,000, respectively, among other variances. The increase for the nine-month period year over year was primarily due to an increase in clinical study costs, expenses related to our DARPA Ebola grant, increased employee headcount, sub-license fee expense based on the up-front payment received from MedImmune, increased outside services related to research and development activities and higher expensed inventory to support clinical trials and partnerships of \$6.6 million, \$4.2 million, \$4.1 million, \$2.0 million, \$1.1 million and \$754,000, respectively. These

increases were offset by lower costs of \$3.0 million incurred for biologics manufacturing and other expenses related to the Roche Agreement, among other variances.

General and Administrative expenses. General and administrative expenses, which include business development expenses, the amortization of intangible assets and patent expenses, for the three and nine months ended September 30, 2015, were \$4.4 million and \$13.2 million, respectively, as compared to \$3.2 million and \$11.6 million for the three and nine months ended September 30, 2014, respectively. The increase for the three-month period year over year was primarily due to an

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increase in corporate and patent legal fees and employee headcount of \$415,000 and \$408,000, respectively, among other variances. The increase for the nine-month period year over year was primarily due to an increase in employee headcount and corporate and patent legal fees of \$1.3 million and \$194,000, respectively, among other variances. Stock-based compensation. Stock-based compensation cost is measured at the grant date, based on the fair value of the award reduced by estimated forfeitures, and is recognized as expense over the employee's requisite service period. Total employee compensation cost for our stock plans for the three and nine months ended September 30, 2015 was \$1.1 million and \$4.6 million, respectively. From these amounts, \$565,000 and \$2.6 million were included in research and development expenses and \$559,000 and \$2.0 million were included in general and administrative expenses, respectively. Total employee compensation cost for our stock plans for the three and nine months ended September 30, 2014 was \$708,000 and \$4.0 million, respectively. From these amounts, \$410,000 and \$2.4 million were included in research and development expenses and \$298,000 and \$1.6 million were included in general and administrative expenses, respectively. The increase for the three and nine-month periods year over year was primarily due to an increase in the number of employee and director stock options and restricted stock units granted.

Change in fair value of common stock warrants. The change in fair value of common stock warrants for the three and nine months ended September 30, 2015 was \$519,000 and \$468,000, respectively, as compared to \$(114,000) and \$204,000 for the three and nine months ended September 30, 2014, respectively. The variance is due to the revaluation of the OncoSec common stock warrants and revaluation of the registered common stock warrants issued by us in March 2013, as well as a fewer number of warrants classified as a current liability due to a significant number of warrants exercised during 2014. We revalue warrants at each balance sheet date to fair value. Warrants that were exercised during the period were revalued the day prior to exercise and reclassified into stockholders' equity upon exercise. If unexercised, the remaining warrants will expire in September 2018.

Gain (Loss) from investment in affiliated entity. The gain (loss) is a result of the change in the fair market value of the investment in GeneOne for the three and nine months ended September 30, 2015.

Gain on sale of assets. The gain on sale of assets is related to the May 2014 sale of animal health assets to Plumblin Life Sciences ("PLS"). The gain is related to the cash received related to the sale (See Note 11).

## Liquidity and Capital Resources

Historically, our primary uses of cash have been to finance research and development activities including clinical trial activities in the oncology, DNA vaccines and other immunotherapy areas of our business. Since inception, we have satisfied our cash requirements principally from proceeds from the sale of equity securities.

### Working Capital and Liquidity

As of September 30, 2015 we had cash and short-term investments of \$170.8 million and working capital of \$165.8 million, as compared to \$93.6 million and \$84.9 million, respectively, as of December 31, 2014. The increase in cash and short-term investments during the nine months ended September 30, 2015 was primarily due to our May 2015 financing and up-front payment of \$27.5 million received from MedImmune, offset by expenditures related to our research and development activities and various general and administrative expenses related to legal, consultants, accounting and audit, and corporate development.

Net cash used in operating activities was \$5.7 million and \$21.7 million for the nine months ended September 30, 2015 and 2014, respectively. The variance was primarily due to the up-front payment received from MedImmune offset by an increase in research and development operating expenses.

Net used in investing activities was \$33.6 million and \$12.6 million for the nine months ended September 30, 2015 and 2014, respectively. The variance was primarily the result of timing differences in short-term investment purchases, sales and maturities.

Net cash provided by financing activities was \$84.2 million and \$71.3 million for the nine months ended September 30, 2015 and 2014, respectively. The increase was related to proceeds received from our May 2015 financing.

On May 5, 2015, we closed an underwritten public offering of 10,925,000 shares of our common stock, including 1,425,000 shares of common stock issued pursuant to the underwriter's exercise of its overallotment option, at the

public offering price of \$8.00 per share. The net proceeds, after deducting the underwriter's discounts and commission and other offering expenses, were \$81.9 million.

On March 4, 2014, we closed an underwritten public offering of 5,452,725 shares of our common stock, including 711,225 shares of common stock issued pursuant to the underwriter's exercise of its overallotment option, at the public offering

price of \$11.60 per share. The net proceeds, after deducting the underwriter's discounts and commission and other offering expenses, were \$59.2 million.

During the nine months ended September 30, 2015, warrants and stock options to purchase 514,712 shares of common stock were exercised for total proceeds to the Company of \$2.4 million.

During the nine months ended September 30, 2014, warrants and stock options to purchase 2,421,311 shares of common stock were exercised for total proceeds to the Company of \$12.1 million.

As of September 30, 2015, we had an accumulated deficit of \$343.1 million. We have operated at a loss since 1994, and we expect to continue to operate at a loss for some time. The amount of the accumulated deficit will continue to increase, as it will be expensive to continue research and development efforts. If these activities are successful and if we receive approval from the FDA to market our DNA vaccine products, then we will need to raise additional funding to market and sell the approved vaccine products and equipment. We cannot predict the outcome of the above matters at this time. We are evaluating potential collaborations as an additional way to fund operations. We believe that current cash and short-term investments are sufficient to meet planned working capital requirements for at least the next twelve months.

### ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

#### Interest Rate Risk

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We are exposed to market risk primarily in the area of changes in United States interest rates and conditions in the credit markets, and the recent fluctuations in interest rates and availability of funding in the credit markets primarily impact the performance of our investments. We do not have any material foreign currency or other derivative financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities.

#### Fair Value measurements

We account for our common stock warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. We classify registered warrants on the condensed consolidated balance sheet as a current liability that is revalued at each balance sheet date subsequent to the initial issuance.

The investment in affiliated entity represents our ownership interest in the Korean based companies, GeneOne and PLS. We report these investments at fair value on the condensed consolidated balance sheet using the closing price of GeneOne and PLS shares of common stock as listed on the Korean Stock Exchange and Korea New Exchange Market, respectively.

Common stock warrants that we have received to purchase shares of OncoSec are classified on the condensed consolidated balance sheet as a long-term asset that is revalued at each balance sheet date subsequent to the initial receipt.

#### Foreign Currency Risk

We have operated primarily in the United States and most transactions during the nine months ended September 30, 2015, have been made in United States dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations, with the exception of the valuation of our equity investments in GeneOne and PLS which are denominated in South Korean Won. We do not have any foreign currency hedging instruments in place.

Certain transactions related to us are denominated primarily in foreign currencies, including Euros, British Pounds, Canadian Dollars and South Korean Won. As a result, our financial results could be affected by factors such as

changes in foreign currency exchange rates or weak economic conditions in foreign markets where we conduct business, including the impact of the existing crisis in the global financial markets in such countries and the impact on both the United States dollar and the noted foreign currencies.

We do not use derivative financial instruments for speculative purposes. We do not engage in exchange rate hedging or hold or issue foreign exchange contracts for trading purposes. Currently, we do not expect the impact of fluctuations in the relative fair value of other currencies to be material in 2015.

#### ITEM 4. CONTROLS AND PROCEDURES

##### Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, which are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our CEO and CFO, our CEO and CFO have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) were effective as of September 30, 2015.

##### Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended September 30, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## Part II. Other Information

### ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material litigation or other material legal proceedings.

### ITEM 1A. RISK FACTORS

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which we filed with the Securities and Exchange Commission on March 13, 2015. You should carefully consider and evaluate each of the following factors as well as the other information in this quarterly report on Form 10-Q, including our financial statements and the related notes, in evaluating our business and prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. If any of the following risks actually occur, our business and financial results could be harmed. In that case, the trading price of our common stock could decline. You should also consider the more detailed description of our business contained in our annual report on Form 10-K for the year ended December 31, 2014.

#### Risks Related to Our Business and Industry

We have incurred losses since inception, expect to incur significant net losses in the foreseeable future and may never become profitable.

We have experienced significant operating losses to date; as of September 30, 2015 our accumulated deficit was approximately \$343.1 million. We have generated limited revenues, primarily consisting of license and grant revenue, and interest income. We expect to continue to incur substantial additional operating losses for at least the next several years as we advance our clinical trials and research and development activities. We may never successfully commercialize our vaccine product candidates or electroporation-based synthetic vaccine delivery technology and thus may never have any significant future revenues or achieve and sustain profitability.

We have limited sources of revenue and our success is dependent on our ability to develop our vaccine and other product candidates and electroporation equipment.

We do not sell any products and may not have any other products commercially available for several years, if at all.

Our ability to generate future revenues depends heavily on our success in:

- developing and securing United States and/or foreign regulatory approvals for our product candidates, including securing regulatory approval for conducting clinical trials with product candidates;
- developing our electroporation-based DNA delivery technology; and
- commercializing any products for which we receive approval from the FDA and foreign regulatory authorities.

Our electroporation equipment and product candidates will require extensive additional clinical study and evaluation, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote our electroporation equipment and product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. If we do not receive regulatory approval for and successfully commercialize any products, we will not generate any revenues from sales of electroporation equipment and products, and we may not be able to continue our operations.

None of our human vaccine product candidates has been approved for sale, and we may not develop commercially successful vaccine products.

Our human vaccine programs are in the early stages of research and development, and currently include vaccine product candidates in discovery, pre-clinical studies and phase I and II clinical studies. There is limited data regarding the efficiency of synthetic vaccines compared with conventional vaccines, and we must conduct a substantial amount of additional research and development before any regulatory authority will approve any of our vaccine product candidates. The success of our efforts to develop and commercialize our vaccine product candidates could fail for a number of reasons. For example, we could experience delays in product development and clinical trials. Our vaccine product candidates could be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances. The products, if safe and effective, could be difficult to manufacture on a large scale or uneconomical to market, or our competitors could develop superior vaccine products more quickly and efficiently or more effectively

market their competing products.

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In addition, adverse events, or the perception of adverse events, relating to vaccines and vaccine delivery technologies may negatively impact our ability to develop commercially successful vaccine products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and autism. These and other claims may influence public perception of the use of vaccine products and could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products.

We will need substantial additional capital to develop our synthetic vaccine and electroporation delivery technology and other product candidates and for our future operations.

Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our vaccine delivery technology and product candidates to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others:

- the progress of our current and new product development programs;
- the progress, scope and results of our pre-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing our products and product candidates;
- the cost of prosecuting, enforcing and defending against patent infringement claims and other intellectual property rights;
- competing technological and market developments; and
- our ability and costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

Additional financing may not be available on acceptable terms, or at all. Domestic and international capital markets have been experiencing heightened volatility and turmoil, making it more difficult to raise capital through the issuance of equity securities. Furthermore, as a result of the recent volatility in the capital markets, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases cease to provide, funding to borrowers. To the extent we are able to raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, the ownership position of existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets. Fluctuating interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long-term value for short-term liquidity.

Our failure to successfully address ongoing liquidity requirements would have a substantially negative impact on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may need to take actions that adversely affect our business, our stock price and our ability to achieve cash flow in the future, including possibly surrendering our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

We depend upon key personnel who may terminate their employment with us at any time and we may need to hire additional qualified personnel in order to obtain financing, pursue collaborations or develop or market our product candidates.

The success of our business strategy will depend to a significant degree upon the continued services of key management, technical and scientific personnel and our ability to attract and retain additional qualified personnel and managers, including personnel with expertise in clinical trials, government regulation, manufacturing, marketing and other areas. Competition for qualified personnel is intense among companies, academic institutions and other organizations. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and product candidates.

We face intense and increasing competition and many of our competitors have significantly greater resources and experience.

If any of our competitors develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific,

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marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive, or result in treatments or cures superior to ours. Many other companies are pursuing other forms of treatment or prevention for diseases that we target. For example, many of our competitors are working on developing and testing H5N1, H1N1 and universal influenza vaccines, and several H1N1 vaccines developed by our competitors have been approved for human use. Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These companies have significantly greater financial and other resources and greater expertise than us in research and development, securing government contracts and grants to support research and development efforts, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and marketing. This may make it easier for them to respond more quickly than us to new or changing opportunities, technologies or market needs. Many of these competitors operate large, well-funded research and development programs and have significant products approved or in development. Small companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies or through acquisition or development of intellectual property rights. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing. Research and development by others may seek to render our technologies or products obsolete or noncompetitive.

If we lose or are unable to secure collaborators or partners, or if our collaborators or partners do not apply adequate resources to their relationships with us, our product development and potential for profitability will suffer.

We have entered into, or may enter into, distribution, co-promotion, partnership, sponsored research and other arrangements for development, manufacturing, sales, marketing and other commercialization activities relating to our products. For example, in the past we have entered into license and collaboration agreements. The amount and timing of resources applied by our collaborators are largely outside of our control.

If any of our current or future collaborators breaches or terminates our agreements, or fails to conduct our collaborative activities in a timely manner, our commercialization of products could be diminished or blocked completely. It is possible that collaborators will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others. Further, we may be forced to fund programs that were previously funded by our collaborators, and we may not have, or be able to access, the necessary funding. The effectiveness of our partners, if any, in marketing our products will also affect our revenues and earnings.

We desire to enter into new collaborative agreements. However, we may not be able to successfully negotiate any additional collaborative arrangements and, if established, these relationships may not be scientifically or commercially successful. Our success in the future depends in part on our ability to enter into agreements with other highly-regarded organizations. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Once news of discussions regarding possible collaborations are known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the entity's announcement of a collaboration with another entity may result in adverse speculation about us, resulting in harm to our reputation and our business.

Disputes could also arise between us and our existing or future collaborators, as to a variety of matters, including financial and intellectual property matters or other obligations under our agreements. These disputes could be both expensive and time-consuming and may result in delays in the development and commercialization of our products or could damage our relationship with a collaborator.

A small number of licensing partners and government contracts account for a substantial portion of our revenue. We currently derive, and in the past we have derived, a significant portion of our revenue from a limited number of licensing partners and government grants and contracts. Revenue can fluctuate significantly depending on the timing of up-front and event-based payments and work performed. If we fail to sign additional future contracts with major licensing partners and the government, if a contract is delayed or deferred, or if an existing contract expires or is

canceled and we fail to replace the contract with new business, our revenue would be adversely affected. We have agreements with government agencies, which are subject to termination and uncertain future funding. We have entered into agreements with government agencies, such as the NIAID and the US Army, and we intend to continue entering into these agreements in the future. Our business is partially dependent on the continued performance by

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these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Many of our government agreements are subject to audits, which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government agreements.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our electroporation equipment, product candidates or future development programs;
- expenses related to corporate transactions, including ones not fully completed;
- addition or termination of clinical trials or funding support;
- any intellectual property infringement lawsuit in which we may become involved;
- any legal claims that may be asserted against us or any of our officers;
- regulatory developments affecting our electroporation equipment and product candidates or those of our competitors;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- if any of our products receives regulatory approval, the levels of underlying demand for our products.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we are unable to obtain FDA approval of our products, we will not be able to commercialize them in the United States.

We need FDA approval prior to marketing our electroporation equipment and products in the United States. If we fail to obtain FDA approval to market our electroporation equipment and product candidates, we will be unable to sell our products in the United States, which will significantly impair our ability to generate any revenues.

This regulatory review and approval process, which includes evaluation of pre-clinical studies and clinical trials of our products as well as the evaluation of our manufacturing processes and our third-party contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our electroporation equipment and product candidates are both safe and effective for each indication for which approval is sought. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the product. We do not know if or when we might receive regulatory approvals for our electroporation equipment and any of our product candidates currently under development. Moreover, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues from such products would be greatly reduced and our business would be harmed.

The FDA has substantial discretion in the approval process and may either refuse to consider our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our electroporation equipment and product candidates. If the FDA does not consider or approve our application, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more

resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our applications for approval, which might significantly harm our business and prospects.



It is possible that none of our products or any product we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our products, generating revenues and achieving and sustaining profitability.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our products may not be predictive of the results of later-stage clinical trials. Results from one study may not be reflected or supported by the results of similar studies. Results of an animal study may not be indicative of results achievable in human studies. Human-use equipment and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical testing. The time required to obtain approval by the FDA and similar foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change. We have not obtained regulatory approval for any human-use products.

Our products could fail to complete the clinical trial process for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our electroporation equipment and a product candidate are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be successful in enrolling a sufficient number of participants in clinical trials;
- we may be unable to demonstrate that our electroporation equipment and a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate that our electroporation equipment and a product candidate presents an advantage over existing therapies, or over placebo in any indications for which the FDA requires a placebo-controlled trial;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of us or third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Delays in the commencement or completion of clinical testing could result in increased costs to us and delay or limit our ability to generate revenues.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. In addition, ongoing clinical trials may not be completed on schedule, or at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial;
- adverse results from third party clinical trials involving gene based therapies and the regulatory response thereto;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- future bans or stricter standards imposed on gene based therapy clinical trials;
- manufacturing sufficient quantities of our electroporation equipment and product candidates for use in clinical trials;



- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- slower than expected recruitment and enrollment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;
- conducting clinical trials with sites internationally due to regulatory approvals and meeting international standards;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- collecting, reviewing and analyzing our clinical trial data; and
- global unrest, terrorist activities, and economic and other external factors.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; and
- lack of adequate funding to continue the clinical trial.

If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our electroporation equipment and our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, delays in the commencement or completion of clinical trials may adversely affect the trading price of our common stock.

We and our collaborators rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we and our collaborators may not be able to obtain regulatory approval for or commercialize our product candidates.

We and our collaborators have entered into agreements with CROs to provide monitors for and to manage data for our on-going clinical programs. We and the CROs conducting clinical trials for our electroporation equipment and product candidates are required to comply with current good clinical practices, or GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or the CROs conducting clinical trials of our product candidates fail to comply with applicable GCPs, the clinical data generated in the clinical trials may be deemed unreliable and the FDA may require additional clinical trials before approving any marketing applications.

If any relationships with CROs terminate, we or our collaborators may not be able to enter into arrangements with alternative CROs. In addition, these third-party CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our on-going clinical programs or perform trials efficiently. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could harm our competitive position. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. Cost overruns by or disputes with our CROs may significantly increase our expenses.

Even if our products receive regulatory approval, they may still face future development and regulatory difficulties. Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene based therapies. Our products will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, record keeping and submission of safety and other post-market information. In addition, manufacturers of drug products and

their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations. If we or a regulatory agency discover previously unknown problems with a product, such as

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adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue Warning Letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

Even if our products receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any electroporation equipment and product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability.

The use of our electroporation equipment and synthetic vaccine candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and autism, and these companies have incurred material costs to defend these claims. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- inability to commercialize our products.

We have obtained product liability insurance coverage for our clinical trials, but our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or

series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our business.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenues.

We currently do not have a sales organization for the marketing, sales and distribution of our electroporation equipment and product candidates. In order to commercialize any products, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We contemplate establishing our own sales force or seeking third-party partners to sell our products. The establishment and development of our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. To the extent we rely on third parties to commercialize our approved products, if any, we will receive lower revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of third parties involved in our commercialization efforts. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize our product candidates which would negatively impact our ability to generate product revenues.

If any of our products for which we receive regulatory approval does not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our electroporation equipment and product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by both the medical community and patient population. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for optimal commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the relative convenience and ease of administration;
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- the prevalence and severity of any actual or perceived adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling, including, for example, potential "black box" warnings
- availability of alternative treatments;
- pricing and cost effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party coverage.

If our electroporation equipment and product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We are subject to uncertainty relating to reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our products' commercial success.

Our ability to commercialize our electroporation equipment and product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our product candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not be able to obtain third-party coverage or reimbursement for our products in whole or in part. Healthcare reform measures could hinder or prevent our products' commercial success.

In both the United States and certain foreign jurisdictions there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell any of our

products profitably. In the United States, the Federal government passed healthcare reform legislation, the Patient Protection and Affordable Care Act, or the ACA. The provisions of the ACA have become or will become effective on various dates. While many of the details regarding the implementation of the ACA are yet to be determined, we believe there will be continuing



trends towards expanding coverage to more individuals, containing health care costs and improving quality. At the same time, the rebates, discounts, taxes and other costs associated with the ACA are expected to be a significant cost to the pharmaceutical industry.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to make and implement healthcare reforms may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the availability of capital; and
- our ability to obtain timely approval of our products.

If we fail to comply with applicable healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business, without limitation. The laws that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, people from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the ACA expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the False Claims Act and the Anti-Kickback Statute to make it easier to bring suit under those statutes;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. Under the ACA, pharmaceutical companies are required to record any transfers of value made to doctors and teaching hospitals and to disclose such data to HHS. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a company may run afoul of one or more laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses

and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we and the contract manufacturers upon whom we rely fail to produce our systems and product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations, we may face delays in the development and commercialization of our electroporation equipment and product candidates.

We manufacture some components of our electroporation systems and utilize the services of contract manufacturers to manufacture the remaining components of these systems and our product supplies for clinical trials. The manufacture of our systems and product supplies requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we or our manufacturers were to encounter any of these difficulties or our manufacturers otherwise fail to comply with their obligations to us, our ability to provide our electroporation equipment to our partners and products to patients in our clinical trials or to commercially launch a product would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product is compromised due to our or our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow.

We may acquire, in-license, develop and/or market additional products and product candidates. The success of these actions depends partly upon our ability to identify, select and acquire promising product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
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difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our and our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In the event of an accident, state or federal authorities may curtail the use of these materials and interrupt our business operations. If we are subject to any liability as a result of our or our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected.

We may be subject to stockholder litigation, which would harm our business and financial condition.

We may have actions brought against us by stockholders relating to past transactions, changes in our stock price or other matters. Any such actions could give rise to substantial damages, and thereby have a material adverse effect on our consolidated financial position, liquidity, or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

Our results of operations and liquidity needs could be materially affected by market fluctuations and general economic conditions.

Our results of operations could be materially affected by economic conditions generally, both in the United States and elsewhere around the world. Concerns over inflation, energy costs, geopolitical issues and the availability and cost of credit have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession. Domestic and international capital markets have also been experiencing heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected. Our future cost of equity or debt capital and access to the capital markets could be adversely affected, and our stock price could decline. There may be disruption in or delay in the performance of our third-party contractors and suppliers. If our contractors, suppliers and partners are unable to satisfy their contractual commitments, our business could suffer. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we may experience losses on these deposits.

#### Risks Related to Our Intellectual Property

It is difficult and costly to generate and protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent, trademark, trade secret, and other intellectual property protection relating to our electroporation equipment and product candidates, as well as successfully defending these intellectual property rights against third-party challenges.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. The laws and regulations regarding the breadth of claims allowed in biotechnology patents has evolved over recent years and continues to undergo review and revision, both in the United States. The biotechnology patent situation outside the United States can be even more uncertain depending on the country. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents, our patents or in third-party patents, nor can we predict the likelihood of our patents surviving a patent validity challenge.



The degree of future protection for our intellectual property rights is uncertain, because legal decision-making can be unpredictable, thereby often times resulting in limited protection, which may not adequately protect our rights or permit us to gain or keep our competitive advantage, or resulting in an invalid or unenforceable patent. For example:

- we, or the parties from whom we have acquired or licensed patent rights, may not have been the first to file the underlying patent applications or the first to make the inventions covered by such patents;
  - the named inventors or co-inventors of patents or patent applications that we have licensed or acquired may be incorrect, which may give rise to inventorship and ownership challenges;
  - others may develop similar or alternative technologies, or duplicate any of our products or technologies that may not be covered by our patents, including design-arounds;
  - pending patent applications may not result in issued patents;
  - the issued patents covering our products and technologies may not provide us with any competitive advantages or have any commercial value;
  - the issued patents may be challenged and invalidated, or rendered unenforceable;
  - the issued patents may be subject to reexamination, which could result in a narrowing of the scope of claims or cancellation of claims found unpatentable;
  - we may not develop or acquire additional proprietary technologies that are patentable;
  - our trademarks may be invalid or subject to a third party's prior use; or
- our ability to enforce our patent rights will depend on our ability to detect infringement, and litigation to enforce patent rights may not be pursued due to significant financial costs, diversion of resources, and unpredictability of a favorable result or ruling.

We depend, in part, on our licensors and collaborators to protect a portion of our intellectual property rights. In such cases, our licensors and collaborators may be primarily or wholly responsible for the maintenance of patents and prosecution of patent applications relating to important areas of our business. If any of these parties fail to adequately protect these products with issued patents, our business and prospects would be harmed significantly.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we or our licensors fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

From time to time, U.S. and other policymakers have proposed reforming the patent laws and regulations of their countries. In September 2011 the America Invents Act (the Act) was signed into law. The Act changed the current "first-to-invent" system to a system that awards a patent to the "first-inventor-to-file" for an application for a patentable invention. The Act also created a procedure to challenge newly issued patents in the patent office via post-grant proceedings and new inter parties reexamination proceedings. These changes may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our product sales, business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Other companies may have or may acquire intellectual property rights that could be enforced against us. If they do so, we may be required to alter our technologies, pay licensing fees or cease activities. If our products or technologies infringe the intellectual property rights of others, they could bring legal action against us or our licensors or collaborators claiming damages and seeking to enjoin any activities that they believe infringe their intellectual property rights.

Because patent applications can take many years to issue, and there is a period when the application remains undisclosed to the public, there may be currently pending applications unknown to us or reissue applications that may later result in issued



patents upon which our products or technologies may infringe. There could also be existing patents of which we are unaware that our products or technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming products or technologies also claimed by us in pending applications or issued patents, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office to determine priority or derivation of the invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications.

If a third party claims that we infringe its intellectual property rights, it could cause our business to suffer in a number of ways, including:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit, the third party's patent is invalid or we have not infringed;
- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a third party's patent;
- we may be enjoined by a court to stop making, selling or licensing our products or technologies without a license from a patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our products so that they do not infringe upon others' patent rights, which may not be possible or could require substantial investment or time.

If any of these events occur, our business could suffer and the market price of our common stock may decline.

#### Risks Related to Our Common Stock

The price of our common stock is expected to be volatile and an investment in our common stock could decline substantially in value.

In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price is expected to be highly volatile and can be subject to substantial drops, with or even in the absence of news affecting our business. Period to period comparisons are not indicative of future performance. The following factors, in addition to the other risk factors described in this annual report, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- developments concerning any research and development, clinical trials, manufacturing, and marketing efforts or collaborations;
- fluctuating public or scientific interest in the potential for influenza pandemic or other applications for our vaccine or other product candidates;
- our announcement of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- fluctuations in our operating results
- announcements of technological innovations;
- new products or services that we or our competitors offer;
- the initiation, conduct and/or outcome of intellectual property and/or litigation matters;
- changes in financial or other estimates by securities analysts or other reviewers or evaluators of our business;
- conditions or trends in bio-pharmaceutical or other healthcare industries;
- regulatory developments in the United States and other countries;
- negative perception of gene based therapy;
- changes in the economic performance and/or market valuations of other biotechnology and medical device companies;
- additions or departures of key personnel;
- sales or other transactions involving our common stock;
- changes in our capital structure;
- sales or other transactions by executive officers or directors involving our common stock;
- changes in accounting principles;
- global unrest, terrorist activities, and economic and other external factors; and



catastrophic weather and/or global disease pandemics.

The stock market in general has recently experienced relatively large price and volume fluctuations. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of the common stock, which could cause a decline in the value of the common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock.

Our amended and restated certificate of incorporation contains provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- the authority of our board of directors to issue shares of undesignated preferred stock and to determine the rights, preferences and privileges of these shares, without stockholder approval;
- all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent; and
- the elimination of cumulative voting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid cash dividends on our common stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude or limit our ability to pay any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

The market price for our shares may not maintain their pre-reverse stock split market price.

On June 5, 2014, we effectuated a 4-for-1 reverse split of the Company's outstanding common stock. We cannot be certain that the reverse split will have a long-term positive effect on the market price of our common stock, or increase our ability to consummate financing arrangements in the future. The market price of our common stock is based on factors that may be unrelated to the number of shares outstanding. These factors include our performance, general economic and market conditions and other factors, many of which are beyond our control. The market price for our post-reverse stock split shares may not rise or remain constant in proportion to the reduction in the number of pre-split shares outstanding before the reverse split. Accordingly, the total market capitalization of our common stock after the reverse split may be lower than the total market capitalization before the reverse split.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

## ITEM 3. DEFAULT UPON SENIOR SECURITIES

Not applicable.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.



ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description of Document
10.1	DNA Cancer Vaccine Collaboration and License Agreement dated as of August 7, 2015 by and between MedImmune, Limited and Inovio Pharmaceuticals, Inc. (filed herewith) (Inovio has applied with the Secretary of the Securities and Exchange Commission for confidential treatment of certain confidential portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.).
31.1	Certification of Chief Executive Officer Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

This exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

\*

PHARMACEUTICALS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Inovio Pharmaceuticals, Inc.

Date: November 6, 2015

By /s/ J. JOSEPH KIM  
J. Joseph Kim  
President, Chief Executive Officer and Director (Principal  
Executive Officer)

Date: November 6, 2015

By /s/ PETER KIES  
Peter Kies Chief Financial Officer (Principal Financial and  
Accounting Officer)